REMARKS

FORMAL MATTERS

Applicants have amended claims 3, 9, and 27. No new matter has been added by way of these amendments.

Claims 1, 3, 9, 10, 14, and 26-30 are currently pending in this application.

CLAIM OBJECTIONS

The Office objected to claim 9, because the word "septicemia" is missing in line 1. *See* Office Action at page 5. Applicants have added the word "septicemia" to claim 9 and therefore request that this objection be withdrawn.

The Office also objected to claims 9, 10, 28, and 29, because they recite non-elected subject matter (species). *Id.* Applicants will consider amending the claims to overcome this objection once patentable subject matter has been indicated in this case. Until then, Applicants respectfully request that the Office hold the objection in abeyance.

CLAIM REJECTIONS UNDER 35 U.S.C. § 102

The Office rejected claims 1, 3, 9, 10, 14, and 26-30 as being anticipated by *Grunfeld* (WO 96/39184). *See* Office Action at page 3. Specifically, the Office alleges that *Grunfeld* teaches "treatment of systematic inflammatory response syndrome, including septicemia, with an anti-PTHrP antibody. Office Action at page 3 (citations omitted). Further, the Office states that the PTHrP antibody "includes a humanized antibody and a human antibody (bottom of page 5)." *Id.* Applicants respectfully traverse.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." M.P.E.P § 2131. In addition, the disclosure in an allegedly anticipating reference must provide an enabling disclosure of the desired subject matter. *See* M.P.E.P. § 2121.01. Contrary to the Office's assertion, the humanized or human antibodies that each are an element of the pending claims are not expressly or inherently described in *Grunfeld*. Even assuming that the humanized and human antibodies are described in *Grunfeld*, *Grunfeld* does not provide an enabling disclosure of such antibodies.

The passages of *Grunfeld* that the Office alleges disclose a humanized and human anti-PTHrP antibody state first that "[t]he polyclonal or monoclonal antibodies may be raised in rabbits, mice, or other animals or tissue cultured cells or **can be products of cells of human origin**." *Grunfeld*, col.3 , ll. 36-38 (Office's emphasis). The passage goes on to state that "[t]hey may also be produced of recombinant DNA technology either in a form identical to that of the native antibody or as chimeric molecules, **constructed by recombination of antibody molecules of man and animal origins** or in other forms chosen to make the antibodies most suitable for use in therapy." *Id.* at ll. 38-43 (Office's emphasis). These broad passages, however, fail to disclose a humanized or human antibody. Merely because an antibody is produced from cells of human origin does not necessarily mean that the antibodies themselves are human. In fact, fully human antibodies are generally produced by transgenic mice. Further, merely because an antibody is constructed by recombination of antibody molecules does not necessarily mean that the antibodies so constructed are humanized

or human. For instance, chimeric molecules, mentioned in the second passage, are antibodies consisting of mouse variable regions and human constant regions and are made using recombinant DNA technology. Chimeric antibodies, however, are not humanized nor human. The passages the Office cited clearly disclose polyclonal, monoclonal, and chimeric antibodies. However, the passages do not disclose human or humanized antibodies, as the pending claims require.

Even assuming that these passages do disclose a human and humanized antibody, the disclosure does not convey sufficient information so that a person skilled in the art is placed in possession of the claimed invention. As section 2121.01 of the M.P.E.P. states "mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation." (*citing Elan Pharm., Inc. v. Mayo Found. for Med. & Educ. Research*, 346 F.3d 1051, 1054 (Fed. Cir. 2003)). Applicants respectfully note that *Grunfeld* does not claim human or humanized PTHrP antibodies, nor does this reference provide any examples. *Grunfeld* also does not provide a sufficient disclosure such that one of ordinary skill in the art would be able to make or use human or humanized anti-PTHrP antibodies. Even assuming *Grunfeld* discloses human and humanized antibodies, the information disclosed in the passages is not sufficient and thus not enabling. Therefore, Applicants respectfully request that the Office withdraw the anticipation rejection of claims 1, 3, 9, 10, 14, and 26-30.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully request the reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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